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PATENTS

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of

Johannes Dirk Anthonie
VAN EMBDEN et al.

Serial No. 09/647,596

GROUP 1655

Filed January 16, 2001

Examiner J. Souaya

METHOD OF INTERSTRAIN
DIFFERENTIATION OF BACTERIA

B/8
17
4/10/01

AMENDMENT

Commissioner for Patents

Washington, D.C. 20231

Sir:

Responsive to the Official Action of March 2, 2001,
please amend the above-identified application as follows:

IN THE SPECIFICATION:

Kindly make of record the attached Sequence Listing,
in paper and diskette formats.

R E M A R K S

Responsive to the requirement for submission of a
sequence listing, as set forth at pages 4 and 5 of the
Official Action, the same is provided herewith, attached to
the present amendment in paper and disk formats. Applicants
hereby state that the content of the paper and disk formats is
the same, and that these introduce no new matter into the
present application.

Responsive to the "restriction" requirement imposed
at Items 1-4 of the Official Action, applicants provisionally

elect Group I, the Escherichia genus, with traverse. The grounds for a traverse are as follows:

Initially, the restriction requirement is improper and unsustainable as a matter of law, in that it does not purport to associate any of claims 1-25 with any of the 15 identified Groups. Consequently, no claims can be withdrawn from consideration on the basis of such an incompletely stated requirement.

Furthermore, as all of claims 1-25 are plainly generic to all of the 15 identified Groups, the requirement stated in the Official Action is by definition not a restriction requirement in the first place; instead, it is at most a requirement for election of species, and applicants' election of the Escherichia genus is made on that understanding.

On the technical merits, the "restriction" requirement is further improper, for the following reasons.

The present application illustrates the applicability of the method in detecting other bacteria than E. coli. In particular, Salmonella identification is also exemplified in the patent application. This Salmonella identification occurred using the same probe as was used for E. coli notwithstanding differences in the Direct Repeats of the bacteria. The correlation between the sequences of the bacteria is sufficient to work the test. This clearly illustrates that identification of both Groups I and III can be performed by the same techniques.

Furthermore, *Escherichia coli* and *Salmonella* are bacteria that are related such that they both belong to the category of bacteria called Enterobacteriaceae. Further, additional members of this category are *Klebsiella* (Group IV), *Enterobacter* (Group V) and *Shigella* (Group II). It is submitted that the correlation within this category of bacteria is also sufficient to warrant identification of strains belonging to the category of Enterobacteriaceae. Thus, identification of Groups I-V is also considered to form a non-restrictable concept.

Finally, the claims are considered to be indivisible by virtue of the fact that a general principle of identification methodology is revealed. The general principle being that Direct Repeats that are present in a particular pattern in the genome of various bacteria are suitable to use as identification markers. The particular pattern is provided for the general group. The location and identity of the Direct Repeats of Groups I-XV are available in Table II and in the prior art. The skilled person can thus easily determine the identity of probes to work with and subsequently carry out the test. The probes from one strain can be used for determining other strains as exemplified in the patent application.

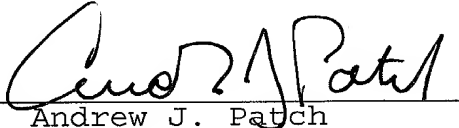
At the top of page 4 of the Official Action, a further election of species requirement was imposed, as to the nucleic acid sequence in Table II corresponding to the bacterium's repeat sequence to be searched along with the group elected. In Table II, it is evident that the second

listed repeat sequence corresponds to the elected Escherichia genus, which sequence is shown as SEQ ID NO. 2 in the attached sequence listing. However, the rationale for this further election of species is not understood, as Table II itself acknowledges this particular repeat sequence as having been disclosed in the identified prior art reference. In that regard, the Examiner will observe that no claim is directed to a single nucleotide sequence of any identity, but rather that the claims are directed to the recited methods, primer pairs, and kits.

From the foregoing discussion, therefore, it is believed to be apparent that the restriction requirement imposed in the outstanding Official Action is improper both as a matter of law and on the facts of this case, and must be withdrawn. Favorable action on the merits of claims 1-25 in their full scope presented, is now respectfully requested.

Respectfully submitted,

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